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PATENTS, TRADEMARKS, COPYRIGHTS & UNFAIR COMPETITION

January 30, 2008

Commissioner For Patents  
Office of Initial Patent Examination  
Customer Service Center  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: Our File: TEVNHC 3.3-2067  
Appln. No. 10/585,912  
Filing Date: September 11, 2007  
Group Art Unit: 1614

Dear Sir:

We are enclosing herewith copies of the filing receipt, executed Declaration and Supplemental Application Data Sheet for the above-identified patent application.

In the "*Applicant(s)*" section, please note that the residence for Yogesh Dandiker should read --**Toronto, CANADA**--, not "Herts, UNITED KINGDOM."

Kindly issue a corrected filing receipt for the above-identified application as soon as possible.

Sincerely yours,

LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK, LLP

ARNOLD H. KRUMHOLZ  
Reg. No. 25,428

AHK/lis  
Enclosures



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
10/585,912	09/11/2007	1614	1430	TEVNHC 3.3-2067	24	4

CONFIRMATION NO. 1400

FILING RECEIPT



530.  
LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090

Date Mailed: 01/23/2008

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

**Applicant(s)**

Austen John Woolfe, Essex, UNITED KINGDOM, Deceased;  
Bernard Woolfe, Epsom, UNITED KINGDOM, Legal Representative;  
Yogesh Dandiker, Herts, UNITED KINGDOM;  
Parizad Elchidana, Mumbai, INDIA;

**Assignment For Published Patent Application**

Norton Healthcare Ltd., London, UNITED KINGDOM

**Power of Attorney:** The patent practitioners associated with Customer Number 000530

**Domestic Priority data as claimed by applicant**

This application is a 371 of PCT/US05/01423 01/15/2005

**Foreign Applications**

UNITED KINGDOM 0400993.2 01/16/2004

**If Required, Foreign Filing License Granted:** 11/27/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 10/585,912**

**Projected Publication Date:** 03/06/2008

**Non-Publication Request:** No

**Early Publication Request:** No

LDUK&M

JAN 25 2008

RECEIVED

**Title**

Stable Gabapentin Compositions

**Preliminary Class**

514

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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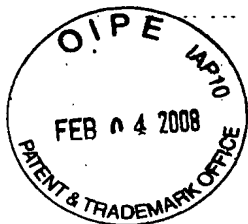
set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

☐ Declaration  
Submitted  
with Initial  
Filing

OR

☒ Declaration  
Submitted after Initial  
Filing (surcharge  
(37 CFR 1.16 (e))  
required)

Attorney Docket Number

TEVNHC 3 3-2067

First Named Inventor

Austen John Woolfe

**COMPLETE IF KNOWN**

Application Number

Not Yet Assigned

Filing Date

Concurrently Herewith

Group Art Unit

N/A

Examiner Name

Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

STABLE GABAPENTIN COMPOSITIONS

(Title of the Invention)

the specification of which

☐ is attached hereto  
OR

☒ was filed on (MM/DD/YYYY) 01/15/2005 as United States Application Number or PCT International

Application No. PCT/US2005/001423 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
0400993.2	GB	01/16/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Please type a plus sign (+) inside this box ☐

PTO/SB/01 (03-01)  
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
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## DECLARATION — Utility or Design Patent Application

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530

Direct all correspondence to: ☒ Customer Number or Bar Code Label **000530** OR ☐ Correspondence address below

Name

Address

City

State

ZIP

Country

Telephone

Email

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
(first and middle (if any))

Austen John

Family Name  
or Surname

Woolfe (DECEASED)

Inventor's  
Signature

Date

Residence: City

Essex

State

Country  
United Kingdom

Citizenship  
United Kingdom

Mailing  
Address:

31 Emberson Way  
North Weald

City

Essex

State

ZIP

CM16 6DL

Country

United Kingdom

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
(first and middle (if any))

Yogesh

Family Name  
or Surname

Dandiker

Inventor's  
Signature

Date

Residence: City

Herts

State

Country  
United Kingdom

Citizenship  
United Kingdom

Mailing  
Address:

17 New Road, Digswell, Welwyn

City

Herts

State

ZIP

Country

United Kingdom

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>DECLARATION</b>	<b>ADDITIONAL INVENTOR(S) Supplemental Sheet</b>
Page 1 of 1	

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Parizad		Elchidana	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mumbai		India	India
Mailing Address: Ivax House, Ivax India Private Limited 76, Makawana Road, Marol Naka			
City	State	Zip	Country
Mumbai		400 059	India
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Bernard		Woolfe (Legal representative)	
Inventor's Signature		Date	
Epsom		6 Sept. 07	
Residence: City	State	Country	Citizenship
Epsom		United Kingdom	United Kingdom
Mailing Address: 1 Elm Grove			
City	State	Zip	Country
Epsom		KT18 7LZ	United Kingdom
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address:			
City	State	Zip	Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address:			
City	State	Zip	Country



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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**☐ Declaration  
Submitted  
with Initial  
Filing

OR

☒ Declaration  
Submitted after Initial  
Filing (surcharge  
(37 CFR 1.16 (e))  
required)

Attorney Docket Number TEVNHC 3.3-2067

First Named Inventor Austen John Woolfe

**COMPLETE IF KNOWN**

Application Number Not Yet Assigned

Filing Date Concurrently Herewith

Group Art Unit N/A

Examiner Name Not Yet Assigned

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(Title of the Invention)

the specification of which

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OR

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Application No.

PCT/US2005/001423

and was amended on  
(MM/DD/YYYY)

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Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
0400993.2	GB	01/16/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:



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 or Bar Code Label

000530

OR ☐ Correspondence address below

Name

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City

State

ZIP

Country

Telephone

Email

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NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
 (first and middle (if any))

Austen John

Family Name  
 or Surname

Woolfe (DECEASED)

Inventor's  
 Signature

Date

Residence: City

Essex

State

United Kingdom

Citizenship

United Kingdom

Mailing  
 Address:

31 Emberson Way  
 North Weald

City

Essex

State

CM16 6DL

ZIP

United Kingdom

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
 (first and middle (if any))

Yogesh

Family Name  
 or Surname

Dandiker

Inventor's  
 Signature

Date

Residence: City

Herts

State

United Kingdom

Citizenship

United Kingdom

Mailing  
 Address:

17 New Road, Digswell, Welwyn

57 EMM AVENUE, TORONTO

City

Herts TORONTO

State

ON

ZIP

M2L 1M9

Country

United Kingdom CANADA

☒

Additional inventors are being named on the

1

supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

PTO/SB/02A (09-04)

Approved for use through 07/31/2006, OMB 0651-0032

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DECLARATION				ADDITIONAL INVENTOR(S) Supplemental Sheet	
				Page 1 of 1	
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
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Inventor's Signature				Date	
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Mumbai			India	India	
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City		State	Zip	Country	
Mumbai			400 059	India	
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Bernard				Woolfe (Legal representative)	
Inventor's Signature				Date	
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Epsom			United Kingdom	United Kingdom	
Mailing Address:		1 Elm Grove			
City		State	Zip	Country	
Epsom			KT18 7LZ	United Kingdom	
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Mailing Address:					
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Inventor's Signature				Date	
Residence: City		State	Country	Citizenship	
Mailing Address:					
City		State	Zip	Country	

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PTO/SB/01 (03-01)  
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# **DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)**

☐ Declaration  
Submitted  
with Initial  
Filing

OR

☒ Declaration  
Submitted after Initial  
Filing (surcharge  
(37 CFR 1.16 (e))  
required)

Attorney Docket Number	TEVNHC 3.3-2067
First Named Inventor	Austen John Woolfe
<b>COMPLETE IF KNOWN</b>	
Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
Group Art Unit	N/A
Examiner Name	Not Yet Assigned

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0400993.2	GB	01/16/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Please type a plus sign (+) inside this box +

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Given Name  
(first and middle [if any])

Austen John

Family Name  
or Surname

Woolfe (DECEASED)

Inventor's  
Signature

Date

Residence: City

Essex

State

United Kingdom

Country

United Kingdom

Citizenship

Mailing  
Address:

31 Emberson Way  
North Weald

City

Essex

State

CM16 6DL

ZIP

United Kingdom

Country

**NAME OF SECOND INVENTOR:**

☐ A petition has been filed for this unsigned inventor

Given Name  
(first and middle [if any])

Yogesh

Family Name  
or Surname

Dandiker

Inventor's  
Signature

Date

Residence: City

Herts

State

United Kingdom

Country

United Kingdom

Citizenship

Mailing  
Address:

17 New Road, Digswell, Welwyn

City

Herts

State

ZIP

United Kingdom

Country

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LD-537

**DECLARATION****ADDITIONAL INVENTOR(S)  
Supplemental Sheet**

Page 1 of 1

**Name of Additional Joint Inventor, if any:**☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))

Family Name or Surname

Parizad

Elchidana

Inventor's  
Signature*Parizad Elchidana*Date *25<sup>th</sup> Oct. 2006*

Residence: City

State

Country

India

Citizenship

India

Mailing  
Address:Ivax House, Ivax India Private Limited  
76, Makawana Road, Marol Naka

City

Mumbai

State

Zip

400 059

Country

India

**Name of Additional Joint Inventor, if any:**☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))

Family Name or Surname

Bernard

Woolfe (Legal representative)

Inventor's  
Signature

Epsom

Date

Residence: City

State

United Kingdom

United Kingdom

Citizenship

Mailing  
Address:

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KT18 7LZ

Country

United Kingdom

**Name of Additional Joint Inventor, if any:**☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))

Family Name or Surname

Inventor's  
Signature

Date

Residence: City

State

Country

Citizenship

Mailing  
Address:

City

State

Zip

Country

**Name of Additional Joint Inventor, if any:**☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))

Family Name or Surname

Inventor's  
Signature

Date

Residence: City

State

Country

Citizenship

Mailing  
Address:

City

State

Zip

Country



## Supplemental Application Data Sheet

### Application Information

Application number::	10/585,912
Filing Date::	07/13/06
Application Type::	Regular
Subject Matter::	Utility
Suggested Group Art Unit::	N/A
CD-ROM or CD-R?::	None
Sequence submission?::	None
Computer Readable Form (CRF)?::	No
Title::	STABLE GABAPENTIN COMPOSITIONS
Attorney Docket Number::	TEVNHC 3.3-2067
Request for Early Publication?::	No
Request for Non-Publication?::	No
Total Drawing Sheets::	0
Small Entity?::	No
Petition included?::	No
Secrecy Order in Parent Appl.?::	No

### Applicant Information

Applicant Authority Type::	Inventor
Primary Citizenship Country::	United Kingdom
Status::	Full Capacity
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Middle Name::	John
Family Name::	Woolfe
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Country of Residence::	United Kingdom
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Country of mailing address:: United Kingdom  
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Applicant Authority Type:: Inventor  
Primary Citizenship Country:: United Kingdom  
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Family Name:: Dandiker  
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Applicant Authority Type:: Inventor  
Primary Citizenship Country:: India  
Status:: Full Capacity  
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Country of Residence:: India  
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76, Makawana Road, Marol Naka  
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Country of mailing address:: India  
Postal or Zip Code of mailing address:: 400 059

#### Correspondence Information

Correspondence Customer Number:: 000530

**Representative Information**

Representative Customer Number:: 000530

**Domestic Priority Information**

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	National Stage of	PCT/US2005/001423	01/15/05

**Foreign Priority Information**

Country::	Application number::	Filing Date::	Priority Claimed::
United Kingdom	0400993.2	01/16/04	Yes

**Assignee Information**

Assignee name:: Norton Healthcare Ltd.  
Street of mailing address:: Albert Basin, Royal Docks  
City of mailing address:: London  
Country of mailing address:: United Kingdom  
Postal or Zip Code of mailing address:: EC16 2QJ